510(k) Summary of Safety and Effectiveness Information
Syva® Emit® II Plus Amphetamines Assay
March 28, 2003

I. MANUFACTURER AND CONTACT INFORMATION

Manufacturer:
Syva Company – Dade Behring Inc.
20400 Mariani Ave.
Cupertino, CA 95014

Contact Information:
Dade Behring Inc.
500 GBC Drive
Newark, DE 19702
Attn: Radames Riesgo
Phone: 305.480.7558
FAX: 305.552.5288

II. DEVICE NAME AND CLASSIFICATION NAME

Trade or Proprietary Name: Syva® Emit® II Plus Amphetamines Assay

Common or Usual Name:
Enzyme Immunoassay, Amphetamine/Methamphetamine
Amphetamine test system (21 CFR §862.3100)
Methamphetamine test system (21 CFR §862.3610)
Class II

III. IDENTIFICATION OF THE LEGALLY MARKETED DEVICE

Syva® Emit® II Plus Monoclonal Amphetamine/Methamphetamine Assay (K993982).

IV. DEVICE DESCRIPTION

The Emit® II Plus Amphetamines Assay is a homogeneous enzyme immunoassay for the qualitative and semiquantitative analysis of amphetamines in human urine.

V. DEVICE INTENDED USE

The Emit® II Plus Amphetamines Assay is a homogeneous enzyme immunoassay with a 300 ng/mL cutoff, 500 ng/mL cutoff or a 1000 ng/mL cutoff (SAMHSA initial test cutoff level). The assay is intended for use in the qualitative and semiquantitative analyses of amphetamines in human urine. Emit® II Plus assays are designed for use with a number of chemistry analyzers.

The Emit® II Plus Amphetamines Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

VI. SUBSTANTIAL EQIVALENCE

The Emit® II Plus Amphetamines Assay is substantially equivalent in intended use and methodology to the Emit® II Plus Monoclonal Amphetamine/Methamphetamine Assay currently in the market. The proposed device, like the predicate device is a monoclonal antibody assay intended for the qualitative and semiquantitative analysis of amphetamines in human urine.

VII. DEVICE PERFORMANCE CHARACTERISTICS

A. 300 ng/mL Cutoff

Method Comparison – Qualitative

The results of one hundred and twenty-four (124) urine specimens obtained with the Syva® Emit® II Plus Amphetamines Assay on the Syva®-30R Biochemical System (K912024) were compared to the results obtained with the reference method, GC/MS. Both methods used a cutoff level of 300 ng/mL for total amphetamines.

Of the sixty-six (66) samples found to be positive by GC/MS (≥ 300 ng/mL total amphetamines), sixty-two (62) were also found positive by Syva□ Emit□ II Plus Amphetamines Assay for a percent agreement of 97% (120/124). Fifty-eight (58) samples were found to be negative by GC/MS (<300 ng/mL total amphetamines) and sixty-two (62) were found to be negative by the proposed device. Four (4) discrepant samples were found by the proposed device. Semiquantitative analysis of the discrepant samples using the proposed device showed values for total amphetamines within -25% of the cutoff.

Qualitative Results 300 ng/mL Cutoff

		Reference Method (GC/MS)	
		Positive	**Negative**
Syva® Emit® II Plus Amphetamines Assay	**Positive**	**62**	**0**
	Negative	**4**	**58**

Percent agreement: 97%

B. 500 ng/mL Cutoff

Method Comparison – Qualitative

The results of one hundred and twenty-four (124) urine specimens obtained with the Syva® Emit® II Plus Amphetamines Assay on the Syva®-30R Biochemical System (K912024) were compared to the results obtained with the reference method, GC/MS. The proposed method used a cutoff level of 500 ng/mL for total amphetamines. While the results of GC/MS were interpreted using the proposed SAMHSA confirmatory guidelines (amphetamine 250 ng/mL or methamphetamine 250 ng/mL and minimum amphetamine 100 ng/mL).

Fifty-nine (59) samples were found to be positive by GC/MS (proposed SAMHSA guidelines) and sixty-two (62) were found positive (≥500 ng/mL) by Syva® Emit® II Plus Amphetamines Assay for a percent agreement of 96% (119/124). Of the sixty-five (65) samples found to be negative by GC/MS, sixty-two (62) were also found to be negative by the proposed device. Five (5) discrepant samples were found. Four (4) of the five discrepant samples were identified as positive by the proposed device and were also found to have more than 500 ng/mL of total amphetamines when they were tested semiquantitatively. However, these four samples were considered negative by GC/MS regardless of the total amphetamines results because they did not meet the acceptance criterion of at least 100 ng/mL of amphetamine of the proposed SAMHSA guidelines for confirmatory test. The other discrepant sample was identified as negative by proposed device and was found to have total amphetamines within -25% of the cutoff level when analyzed semiquantitatively.

Qualitative Results 500 ng/mL Cutoff

		Reference Method (GC/MS)	
		Positive	**Negative**
Syva® Emit® II Plus Amphetamines Assay	**Positive**	**58**	**4**
	Negative	**1**	**61**

Percent agreement: 96%

C. 1000 ng/mL Cutoff

Method Comparison – Qualitative

The results of one hundred and twenty four (124) urine specimens obtained with the Syva® Emit® II Plus Amphetamines Assay on the Syva®-30R Biochemical System (K912024) were compared to GC/MS as reference methodology. The proposed method used a cutoff level of 1000 ng/mL while the reference method used a cutoff level of 500 ng/mL according to SAMHSA confirmatory guideline (amphetamine 500 ng/mL or methamphetamine 500 ng/mL plus minimum amphetamine 200 ng/mL). In addition, the Syva® Emit® II Plus Amphetamines Assay was compared to the Syva® Emit® II Plus Monoclonal Amphetamine/Methamphetamine Assay (K993982) by evaluating the same number of urine

specimens on the Syva®-30R Biochemical System. For this comparative study, both devices used a cutoff level of 1000 ng/mL for total amphetamines.

Sixty-five (65) samples were found to be positive by GC/MS (SAMHSA confirmatory guidelines) and sixty-two (62) were found positive (≥1000 ng/mL) by Syva® Emit® II Plus Amphetamines Assay for a percent agreement of 86% (107/124). Fifty-nine (59) samples were found to be negative by GC/MS and sixty-two (62) were found to be negative by the proposed device. Seventeen (17) discrepant samples were found. Seven (7) of the discrepant samples that were found positive by the proposed device showed semiquantitative results over 1000 ng/mL, however, they were considered negative by GC/MC because they did not meet the minimum 200 ng/mL amphetamine criterion for SAMHSA confirmatory test. Ten (10) discrepant samples were found to be negative by the proposed test and were found to have total amphetamines values within the -25% and the cutoff.

Qualitative Results 1000 ng/mL Cutoff

		Reference Method (GC/MS)	
		Positive	**Negative**
Syva® Emit® II Plus Amphetamines Assay	**Positive**	**55**	**7**
	Negative	**10**	**52**

Percent agreement: 86%

Sixty (60) samples were found to be positive by the comparative method and sixty-two (62) were found positive (≥1000 ng/mL) by Syva® Emit® II Plus Amphetamines Assay for a percent agreement of 97% (120/124). Sixty-four (64) samples were found to be negative by the comparative method and sixty-two (62) were found to be negative by the proposed device. Four discrepant samples were found. Three (3) of the discrepant samples that were found to be positive by the proposed device, were confirmed positive by GC/MS results. One (1) discrepant samples found to be negative by the proposed device was also confirmed as negative by GC/MS results.

Qualitative Results 1000 ng/mL Cutoff

		Comparative Method	
		Positive	**Negative**
Syva® Emit® II Plus Amphetamines Assay	**Positive**	**59**	**3**
	Negative	**1**	**61**

Percent agreement: 97%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 6 2003

Ms. Rebecca S. Ayash
Director, Regulatory Affairs & Compliance
Dade Behring, Inc.
500 GBC Drive
Newark, DE 19702

Re: k031004
Trade/Device Name: Emit® II Plus Amphetamines Assay
Regulation Number: 21 CFR 862. 3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ
Dated: March 28, 2003
Received: March 31, 2003

Dear Ms Ayash:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031004

Device Name: Emit® II Plus Amphetamines Assay

Indications for Use:

The Emit® II Plus Amphetamines Assay is a homogeneous enzyme immunoassay with a 300 ng/mL cutoff, 500 ng/mL cutoff or a 1000 ng/mL cutoff (SAMHSA initial test cutoff level). The assay is intended for use in the qualitative and semiquantitative analyses of amphetamines in human urine. Emit® II Plus assays are designed for use with a number of chemistry analyzers.

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Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031004

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-The-Counter-Use** _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**